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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/585,023 06/01/00 DALLA-FAVERA

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EXAMINER

HM12/1206

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MCGARRY, S

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/585,023

Applicant(s)

DALLA-FAVERA, RICCARDO

Examiner

Sean McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-92,98,102 and 103 is/are pending in the application.
- 4a) Of the above claim(s) 90-92,98,102 and 103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 88 and 89, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the inventions are not independent. This is not found persuasive because The inventions have been shown to be distinct invention in the restriction mailed 10/6/00. Further, the inventions are independent since, for example, the antibodies of Group II are drawn specifically to a protein with a specific sequence and the proteins of group I are not limited (claim 88) to any sequence and would include any protein that may be considered a MUM-1 protein.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 90-92, 98, 102, and 103 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

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The instant specification contains applicable sequences in Figures 2B, 5B-1, 5B-2, 5B-3, 6A and 6B. These sequences have not been properly identified by sequence identifiers in the specification. Further there are references to "(SEQ. ID NO)" on pages 20 and 21, for example. Applicant is required to fully comply with the requirements of 37 CFR 1.821 through 1.825 in the response to this Official Action.

4. The disclosure is objected to because of the following informalities: On pages 19 and 20, for example there are references to ATTC deposits were no deposit number is disclosed. Applicant should review the entire specification and ensure that all referred ATTC deposits are properly identified.

Appropriate correction is required.

5. Claims 88 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 89 recites "... as shown in Figure 5B (SEQ. ID NO: 14)." This language is unclear since there is no Figure 5B *per se*, but Figures 5B-1, 5B-2, and 5B-3.

Claim 88 claims a MUM-1 protein. It is unclear what the scope of this claim is. The specification does not provide a specific definition of a MUM-1 protein. It is unclear, with the use of the "MUM-1" acronym, whether for example the claim is intended to be limited to the

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sequence of SEQ ID NO: 14 or would it encompass a group of proteins that are designated "MUM-1" of which the means of such designation are unclear.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 88 and 89 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsuyama et al [NAR Vol. 23(12):2127-2136, 1995, cited by applicant].

Matsuyama disclose a protein LSIRF that is the same as that disclosed in SEQ ID NO: 14. Matsuyama disclose that the protein was detected in a Western blot. It should also be noted that applicant appears to admit (Page 40 in reference to Matsuyama et al.) that the gene disclosed by Matsuyama is the same as the instantly claimed "MUM-1".

8. Claim 88 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to a "MUM-1" protein. The instant specification discloses the putative sequence of one "MUM-1" protein. The specification does not disclose any other

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MUM proteins such that one of skill in the art would immediately envision the structure of any other MUM-1 proteins. The disclosure of one "MUM-1" protein sequence does not show one in the art that at the time the application was filed, applicant had possession of the claimed invention.

9. Claims 88 and 89 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The specification discloses only a putative amino acid sequence for the "MUM-1" gene. There is no guidance or direction and no working example that would show by correlation any biological activity, function or sequence for any "MUM" genes. The specification describes the isolation of a nucleic acid termed MUM-1. The nucleic acid sequence was isolated by its association with chromosomal translocations. The specification as filed does not provide any guidance or direction and provides no working examples that would show by correlation any biological activity for the exemplified MUM-1 protein. The specification as filed provides no characterization of the claimed protein other than a description of the nucleic acid sequences encoding it, and a putative amino acid sequence from the MUM-1 nucleic acid sequence. The claimed invention is drawn to a "MUM" protein where the specification generically defines "MUM" as any gene rearranged in 14q+ chromosomal abnormalities (this definition would include translocations, crossovers, deletions, insertions, etc). It is unclear how one would use a protein putatively expressed by a nucleic acid whose characterization is limited to location and northern blot analysis.

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Claims 88 and 89 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sean McGarry

November 29, 2000


SEAN MCGARRY
PATENT EXAMINER
TC 1600